UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA
ex rel. BROOK JACKSON,

Plaintiff,

- v -

VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC,

Defendants.

CASE NO. 1:21-CV-00008-MJT

ORAL ARGUMENT REQUESTED

ICON PLC'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ICON PLC'S MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT

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Defendant ICON plc ("ICON") respectfully submits this Reply memorandum in further support of Defendants' Motion to Dismiss Counts I and II of the Amended Complaint pursuant to the Federal Rules of Civil Procedure 9(b) and 12(b)(6). ICON joins and incorporates by reference Defendants Pfizer's and Ventavia's Reply memoranda.[1]

PRELIMINARY STATEMENT

Relator's Opposition to ICON's Motion to Dismiss confirms the paucity of the allegations against ICON. As in the Amended Complaint, ICON is again treated largely as an afterthought, shoe-horned into a wildly speculative and totally unsupported "scheme." Relator devotes many pages of her brief to politically charged, scientifically baseless claims—including assertions that the vaccine "poses more risks than benefits" and "is neither safe nor effective" and the frequent use of scare quotes around the word "vaccine." Yet the central question here is not a political one, but a straightforward legal one: has Relator adequately alleged FCA claims against ICON? As Relator's Opposition confirms, she has not.

First, the Amended Complaint does not meet the pleading standards of Rule 9(b). The Opposition concedes that Relator is required to satisfy Rule 9(b) to plead an FCA claim, but does not demonstrate that she alleged a false claim with specificity. Relator lists "relevant samples" of alleged violations of clinical trial protocols and FDA regulations by ICON, but even if this alleged misconduct could support an FCA claim—and it cannot—the "relevant samples" are all generic and conclusory, and many are contradicted elsewhere in the Amended Complaint.

Second, the Amended Complaint fails to allege a false claim or a false statement causing a false claim made by ICON, as the FCA requires. As the Opposition acknowledges, the Amended Complaint does not allege the *sine qua non* of FCA liability: a false claim. Relator's attempts to

[1] ICON adopts the defined terms set forth in its Motion to Dismiss Relator's Amended Complaint and Memorandum of Law in Support [Dkt No. 51] ("ICON's Motion to Dismiss" or "ICON MTD"). Unless noted otherwise, emphasis is added and internal citations and quotations marks are omitted.

allege false statements fare no better. Her allegations of violations of trial protocols and FDA regulations are not false statements. And she does not plausibly allege that the Form FDA-1572 that ICON provided to Pfizer (not the government) constituted a false statement causing payment of a false claim.

Third, the Amended Complaint fails to allege scienter. The Opposition practically ignores this required element of an FCA claim. Relator does not sufficiently allege that ICON had actual or constructive knowledge of any alleged trial procedure violations or otherwise acted with reckless disregard, and most crucially, does not allege scienter as to any false claim.

Finally, Relator should not be granted leave to amend, as her proposed amendments would be futile.

For all of these reasons, the Court should dismiss Counts I and II of the Amended Complaint with prejudice.

ARGUMENT

I. RELATOR'S ALLEGATIONS FAIL TO SATISFY RULE 9(b)'S PLEADING STANDARDS

Relator concedes that her pleading must satisfy the Rule 9(b) pleading standard and contends that she has "pled with particularity that each Respondent made or caused to be made false statements with requisite scienter, that those statements were material to the Government's decision to pay, and those statements caused the government to pay." (Opp. at 4). But Relator does not come close to satisfying Rule 9(b)'s pleading standards as to each defendant, and certainly not as to ICON. In order to do so, she must allege "as to each individual defendant 'the nature of the fraud, some details, [and] a brief sketch of how the fraudulent scheme operated, when and where it occurred, and the participants.'" *Hernandez* v. *CIBA-GEIGY Corp. USA,* 2000 WL 33187524, at *5 (S.D. Tex. Oct. 17, 2000) (quoting *Askanase* v. *Fatjo,* 148 F.R.D. 570, 574 (S.D. Tex. May 3, 1993)); *see also Unimobil 84, Inc.* v. *Spurney*, 797 F.2d 214, 217 (5th Cir.

1986) ("[G]eneral allegations, which do not state with particularity what representations each defendant made, do not meet [Rule 9(b)'s] requirement."). The handful of allegations in the Amended Complaint against ICON are entirely generic, conclusory, and based on unsupported speculation—falling far short of the Rule 9(b) standard—and Relator's Opposition, which largely just restates these inadequate allegations, does not change this.

Relator states that she need not "describe all actions, dates, participants and other details of the alleged fraud at the pleading stage." (Opp. at 4 (quoting *United States ex rel. Bechtold* v. *Asfora,* No. CIV 16-4115, 2020 WL 5547920, at *2 (D.S.D. Sept. 16, 2020)). She still must, however, plead the ***details*** of the alleged false claim, including "the time, place and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby." *United States ex rel. Reddell* v. *DynCorp Int'l, LLC*, No. 1:14-cv-86, 2019 WL 12875471, at *4 (E.D. Tex. Mar. 20, 2019). As discussed *infra*, Relator does not allege a false claim, much less with the level of particularity that Rule 9(b) requires. This failure alone is dispositive.

The Opposition argues that, to meet Rule 9(b)'s heightened pleading standard, all Relator must do is allege a fraudulent scheme and provide a few "representative samples" of the scheme. (Opp. at 3 (quoting *United States ex rel. Prather* v. *Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 830 (6th Cir. 2018)). Relator purports to list some of these "representative samples" as to ICON in her Opposition (Opp. 15-16), but each only demonstrates the deficiency of the allegations. For example, the Opposition points to certain paragraphs of the Amended Complaint alleging that authority was delegated to ICON. But these allegations are completely lacking in the "who, what, when, where, and how" required to allege a false claim under Rule 9(b). *United States ex. rel Headen* v. *Abundant Life Therapeutic Services Texas, LLC*, 2019 WL 1930274, at *6, *9 (S.D. Tex. Apr. 30, 2019). There is no explanation of what ICON's responsibility to

"ensure[] trial protocol compliance" or "quality checking of the data" entailed (Am. Comp. ¶¶ 4, 15); what degree of management Pfizer delegated to ICON when it delegated "some management" (*id.* ¶ 137); or the specifics of how "some management" was delegated between ICON and Ventavia (*id.* ¶ 137)—just a vague assertion that these responsibilities were given to both ICON and its co-defendants. And none of these allegations identify any element of fraud or a false claim.

The Opposition's list of purported representative samples continues, listing various alleged "red flags" that ICON allegedly ignored. These examples also lack the "who, what, when, where, and how" required by Rule 9(b). For instance, Relator cites to allegations that Ventavia included ineligible participants in the clinical trial, "violations [that] would be obvious from the source documents" and which "ICON ignored[."] (Am. Compl. ¶ 151). However, Relator does not allege ***why*** this violation would have been "obvious" to ICON or ***how*** ICON "ignored" it, and indeed the supporting exhibit filed with the Amended Complaint demonstrates that ICON actually flagged the issue and requested follow up. *See* ICON MTD at 13-14 (discussing Am. Compl. ¶ 151 and Ex. 11). Relator includes multiple examples that follow this conclusory pattern: allegations that another defendant violated protocol and that the violation was hidden from ICON, but that ICON should have acted because such violation was "obvious" (without any explanation of ***why*** it was obvious) from vaguely described (if they are described at all) source documents.[2] And, as noted above, many of the allegations of ICON ignoring red flags that the Opposition lists

[2] *See, e.g.*, Am. Compl. ¶ 177 (speculating that if issues with using the wrong needle size were "not concealed via needle size falsification by Ventavia" then ICON "had constructive notice of [the issues] via source documents"); ¶ 187 (alleging that "Ventavia even falsified some patient data to cover protocol violations or missing data" resulting in unspecified "obvious warning signs of documentation failures").

actually demonstrate that ICON was acting appropriately in its oversight role, and not engaged in any invented fraudulent scheme.[3]

II. THE AMENDED COMPLAINT FAILS TO ALLEGE THAT ICON PRESENTED A FALSE CLAIM OR MADE A FALSE STATEMENT MATERIAL TO A FALSE CLAIM

The FCA prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" or "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim[.]" U.S.C. § 3729(a)(1)(A), (B). The Amended Complaint fails to allege either a "false claim" or a "false statement" as to ICON, and the Opposition does not change this. Relator's claims that ICON made a false claim or statement do not even pass muster under the more liberal pleading standard of Rule 8(a)(2), let alone the exacting standard of Rule 9(b).

As an initial matter, and as the Opposition does not dispute, Relator does not allege that ICON submitted any claim requesting payment from the United States. The failure is fatal to Relator's claims against ICON. The Opposition concedes that the only claim for payment submitted to the government were invoices submitted by Pfizer. (Opp. at 10). Relator fails to allege, however, that even those invoices contained anything false or fraudulent. *See* Pfizer Mot. at 20-25; Pfizer Reply Br. at 3. And, as explained further in Pfizer's Reply Brief, Relator's theory of fraudulent inducement—impermissibly raised for the first time as attorney argument in the Opposition—is unsupported by the allegations in her Amended Complaint. *See* Pfizer Reply Br. at 3-5. Relator's failure to allege a false claim—the "*sine qua non* of liability under the FCA," *United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 326 (5th Cir. 2017)—is

[3] *See, e.g.*, Am. Compl. ¶ 158 (acknowledging that ICON sent an email intended only for unblinded staff to an unblinded Ventavia staff member); ¶ 178 ("ICON noticed the issue and informed Ventavia."); ¶ 191 ("ICON also directly questioned missing blood collection and processing times..."); ¶ 254 (Relator identified "100 outstanding queries from ICON about missing or inconsistent data"); *see also* ICON MTD at 14-15 (discussing exhibits attached to the Amended Complaint that reflect ICON personnel properly and adequately carrying out oversight roles).

dispositive of both counts against ICON. *See United States ex rel. Nunnally* v. *W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 894 (5th Cir. 2013) (affirming dismissal where complaint did "not identify a single claim submitted by [defendant] for services rendered pursuant to an illegal referral, let alone one for which [defendant] expressly certified its compliance with federal law"); *United States ex rel. Sonnier* v. *Standard Fire Ins. Co.*, 84 F. Supp. 3d 575, 585–86 (S.D. Tex. Jan. 29, 2015) ("The relator must, however, allege facts showing that 'the defendant made a false record or statement [material to] a false or fraudulent claim paid by the Government" (quoting 31 U.S.C. § 3729(a)(1)(B))).

Nor does Relator come anywhere close to alleging that ICON made any false records or statements in violation of § 3729(a)(1)(B). Relator's theory of "false statement" as to ICON appears to be that ICON turned a blind eye to alleged deficiencies in the clinical trial as part of a fraudulent scheme, thereby transforming Form FDA-1572—not even alleged in the Amended Complaint to have been submitted to the FDA—into a false statement. (Opp. at 15-16). None of this is supported by the generic and conclusory assertions, inadmissible group pleading, and contradictory allegations that actually comprise the Amended Complaint (and its attached exhibits).[4] At most, Relator alleges that (i) ICON provided a signed form to Pfizer agreeing to comply with certain trial protocols, and (ii) Relator, during her brief stint working for Ventavia, witnessed ICON personnel monitoring trial procedures in accordance with the form. She then baselessly speculates that, after she left, and at the two trial sites where she worked as well as the hundreds she did not, ICON violated trial procedures and regulatory requirements, thus retroactively transmuting the form into a false statement to the government.

[4] *See United States ex rel. Riley* v. *St. Luke's Episcopal Hosp.*, 355 F.3d 370, 377 (5th Cir. 2004) ("If an allegation is contradicted by the contents of an exhibit attached to the pleading, then indeed the exhibit and not the allegation controls.").

Even if the Amended Complaint ***did*** adequately plead that ICON shirked its oversight duties for the clinical trial, this is not a "false statement," under the FCA. Alleged "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA." *United States ex rel. Thompson* v. *Columbia/HCA Healthcare Corp.,* 125 F.3d 899, 902 (5th Cir. 1997); *see also Universal Health Servs. Inc.* v. *United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) ("The False Claims Act is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations."). It is the false ***certification*** of compliance, where certification is a prerequisite to obtaining a government benefit, that creates liability under the FCA. *Thompson.*, 125 F.3d at 902. The allegations of violations by ICON of clinical trial protocol and FDA regulations—even if taken as true—are insufficient, because Relator does not—and cannot—allege that ICON certified compliance as a prerequisite for government payment.

Relator contends that the Amended Complaint does meet this requirement, because ICON "certified [compliance] in its Form FDA-1572 . . . [which] it submitted to the FDA as part of Pfizer's overall EUA application and therefore the falsified certifications therein constitute numerous false statements to the government." (Opp. at 16). This argument is false. The Amended Complaint does ***not*** allege that ICON submitted its signed Form FDA-1572 to the government; it alleges that ICON submitted it to Pfizer. (Am. Compl. ¶¶ 62, 277). The Amended Complaint does ***not*** allege that ICON certified in the Form FDA-1572 that it would report "changes in research activity" or "unanticipated problems" (or anything at all) to the FDA; it alleges that ICON certified it would report these things to Pfizer's internal review board (*Id.*).

The Opposition asserts that the Form FDA-1572 was a "but-for cause" of the government's payment decision. (Opp. at 17). But this is completely unsupported by the pleadings. The Amended Complaint simply does not allege that ICON's signature of the Form FDA-1572 was a prerequisite for any government payment; all it alleges is that "[t]he sponsor [Pfizer] must obtain a

signed Form FDA-1572 from each contract investigator [ICON and Ventavia]." (Am. Compl. ¶ 62). And indeed the Amended Complaint could not make such an allegation. As discussed in ICON's Motion to Dismiss, the FDA's website expressly notes that submitting Form FDA-1572 to the FDA is not mandatory; the sponsor is merely required to collect the form from the investigator.[5] The Opposition does not dispute this.

Additionally, ICON's Motion to Dismiss cited the only reported case where a relator attempted to premise an FCA claim on the submission of a Form FDA-1572. There, relator alleged that the form (along with other forms submitted by defendants) "constituted certifications of compliance with all requirements and conditions" of a government grant. *United States ex rel. Gross* v. *AIDS Research Alliance-Chicago*, 415 F.3d 601, 603-04 (7th Cir. 2005). As is the case here, relator failed to allege "how the filing of any of these forms related to payment of grant money," and instead alleged that the form "constituted certifications of compliance." *Id.* The court found that relator failed to plead that defendant made a false statement "to get a false or fraudulent claim paid or approved by the Government" with the requisite specify under Rule 9(b). *Id*. at 604. Again, the Opposition does not respond. Plaintiff fails to allege that ICON's completion of Form FDA-1572 caused the government to make any payment to anyone.

III. THE AMENDED COMPLAINT FAILS TO ADEQUATELY ALLEGE THAT ICON ACTED WITH THE REQUISITE SCIENTER

To plead a claim under the FCA, Relator must plead that the defendant ***knowingly*** made a false claim or a false statement material to a false claim, and Section 3729 expressly defines this scienter element to include "(1) actual knowledge of the [falsity of the] information; (2) acts in

[5] *See* ICON MTD at 6, n.7 ("Does 1572 need to be submitted to the FDA? No. Although the sponsor is required to collect the 1572 from the investigator, FDA does not require the form to be submitted to the agency. Many sponsors submit the 1572 to FDA, however, because it collects, in one place, information that must be submitted to FDA under 21 CFR 312.23(a)(6)(iii)(b)") (quoting "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, May 2010, https://www.fda.gov/media/78830/download).

deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." *United States ex rel. Longhi* v. *Lithium Power Technologies, Inc.*, 575 F.3d 458, 467 (5th Cir. 2009). The Opposition's brief discussion of scienter does not even attempt to contend that ICON knowingly made a false claim or false statement to the government, arguing only that ICON acted with scienter as to "the falsity of the information provided by Ventavia." (Opp. at 24). Even if this were enough, the Amended Complaint contains no allegations that ICON acted with actual knowledge, deliberate ignorance, or reckless disregard as to violations of trial procedures.

As to actual knowledge, the Amended Complaint pleads the opposite, with repeated allegations that alleged violations were actively ***hidden*** from ICON. *See* ICON MTD at 18-19. Relator's Opposition restates these allegations, noting that information was not reported to ICON and that alleged protocol deviations were "bur[ied]" as "notes to the file." (Opp. at 12-13). Relator does not address the irony of this argument in her Opposition.

As to deliberate ignorance (also defined as "constructive knowledge"), Relator must show that ICON "buried [its] head in the sand" and "failed to make simple inquiries which would alert [it] that false claims were being submitted." *United States ex rel. Longhi* v. *Lithium Power Technologies., Inc.*, 513 F. Supp. 2d 866, 875-76 (S.D. Tex. Sept. 27, 2007). Relator does not provide any specifics as to how ICON failed to undertake a "reasonable and prudent" inquiry or failed to meet its "limited duty to inquire," *id.*, and indeed, the exhibits to the Amended Complaint refute any suggestion that ICON "buried its head in the sand." *See* ICON MTD at 19-20.

Finally, as to reckless disregard Relator must allege that "the submitted claims . . .are prepared in such a sloppy or unsupervised fashion that resulted in overcharges to the Government." *Longhi*, 513 F. Supp. 2d at 876 (quoting *United States* v. *Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997)). Her conclusory assertions that ICON "abdicated [its] duty" to monitor the

clinical trial falls far short of meeting this standard. Relator's pleadings make clear that ICON acted appropriately in its supervisory role. The alleged regulatory and protocol violations that Relator points to as evidence of scienter are—at most—the sort of "[i]nnocent mistakes, mere negligence, or even gross negligence" that courts have found "not actionable under the False Claims Act." *Longhi*, 513 F. Supp. 2d at 875–76; *see also* ICON MTD at 20.

Ultimately, even if Relator ***had*** adequately alleged that ICON acted with scienter as to alleged violations of trial procedures (she did not), that does not establish that ICON acted with scienter as to the ***material falsity of claims made to the government***, which is what is actually at issue in this *qui tam* action. *See* ICON MTD at 20.

IV. GRANTING LEAVE TO AMEND WOULD BE FUTILE

Rule 15(a)(2) provides that courts should "freely give" leave to amend "when justice so requires," however "leave to amend is by no means automatic." *Halbert* v. *City of Sherman, Tex.,* 33 F.3d 526, 529 (5th Cir. 1994). When deciding whether to grant leave, courts have broad discretion and may consider, *inter alia*, "futility of the amendment." *Dussouy* v. *Gulf Coast Inv. Corp.,* 660 F.2d 594, 598 (5th Cir.1981). Relator's proposed amendment in this case would be futile. The complaint's chief defect is that it pleads alleged regulatory violations, not false claims. Yet Relator offers to "expand the detail" of her complaint with respect to the alleged regulatory violations only. (Opp. at 36.). Whatever the content of these proposed additions, they cannot create false claims, nor can they change the Government's actual behavior in response to Relator's allegations. Leave to amend is not warranted.

CONCLUSION

For the foregoing reasons, in addition to those set forth in the reply briefs filed by Pfizer and Ventavia, ICON respectfully requests that the Court dismiss the claims asserted against ICON in their entirety with prejudice.

Date: September 20, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2022, a copy of the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all known counsel of record by operation of the Court's electronic filing system.

/s/ Scott L. Davis
Scott L. Davis